



Instructions for Use

US IVD HCCA portioned

Purified matrix substance for use with MALDI Biotyper CA Systems



Language: US-en

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1 Intended Use

US IVD HCCA portioned is an in- vitro-diagnostic product which must be used when processing test organisms for identification on the MALDI Biotyper CA System. US IVD HCCA portioned must be dissolved in accordance with the instructions provided using the recommended solvent.

Caution: Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner.

2 Product Description


US IVD HCCA portioned (referred to as 'US IVD HCCA'; HCCA = α -Cyano-4-hydroxycinnamic acid) enables easy and convenient preparation of MALDI matrix solution for MALDI Biotyper CA measurement and identification of test organisms. US IVD HCCA is soluble in standard solvent (see section 4). Each tube contains 2.5 ± 0.3 mg matrix, enabling fast preparation of the desired concentration simply by adding the recommended volume of standard solvent.

3 Inspection, Storage and Stability


3.1 Inspection upon Receipt

Check the US IVD HCCA package upon receipt. If the tubes are damaged do not use.

3.2 Storage on Arrival

+2°C		+8°C	US IVD HCCA is shipped at ambient temperature but must be stored at 2–8°C. Do not use beyond expiration date noted on the package.
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3.3 Storage after Solubilization

+20°C		+25°C	Dissolved US IVD HCCA solution is stable at controlled room temperature (20–25°C) for up to one week.
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3.4 Risk and safety information



US IVD HCCA is classified as a hazardous chemical: WARNING (H315, H319, H335)¹

For more information, read the Material Safety Data Sheet available for download at www.bruker.com/care.

Additional chemicals may be required for procedures described in these Instructions for Use. Carefully read the Material Safety Data Sheet provided by the supplier and follow general safety regulations when handling chemicals or biohazardous material.

¹ H315: Causes skin irritation; P264: Wash hands thoroughly after handling; P280: Wear protective gloves/protective clothing/eye protection/face protection; P302+P352: IF ON SKIN: Wash with soap and water; P321: Specific treatment (see First aid measures in the MSDS); P332+P313 If skin irritation occurs: Get medical advice/attention; P362+P364: Take off contaminated clothing and wash it before reuse. H319: Causes serious eye irritation; P264: Wash hands thoroughly after handling; P280: Wear protective gloves/protective clothing/eye protection/face protection; P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing; P337+P313 If eye irritation persists get medical advice/attention. H335: May cause respiratory irritation; P261: Avoid breathing dust/fume/gas/mist/vapors/spray; P271: Use only outdoors or in a well-ventilated area; P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing; P312: Call a POISON CENTER or doctor/physician if you feel unwell; P403+P233: Store in a well-ventilated place. Keep container tightly closed; P405: Store locked up; P501: Dispose of contents/container in accordance with local/regional/national/international regulations.

4 Preparation of US IVD HCCA Solution

Chemicals and Materials Required

- Standard solvent (acetonitrile 50%, water 47.5% and trifluoroacetic acid 2.5%) from Sigma- Aldrich, which has been tested by Bruker and is recommended for use when dissolving US IVD HCCA.

Equipment and Tools Required but not Provided

- Vortex mixer, pipettes, pipette tips.

Preparation of US IVD HCCA solution

1. Add 250 μ L standard solvent to the screw cap tube containing US IVD HCCA (final concentration: 10 mg US IVD HCCA/mL) and close the tube.
2. Shake and vortex until completely dissolved.
3. Shake the contents down.
4. Store at controlled room temperature for up to 1 week.

5 US IVD HCCA Sample Preparation Procedure

Note Poor sample preparation will impact product performance and will result in low resolution and poor reproducibility. The generation of ions through MALDI depends on the presence of an optimal ratio of matrix substance to analyte. For best results, use all materials as directed and use only chemicals recommended for use by Bruker (for example, CHROMASOLV® LC-MS solvents).

The procedures below are used for identification of test organisms using the MALDI Biotyper CA System.

Direct Transfer sample preparation method

1. Select two positions on a US IVD 48 Spot Target (cross-joint positions are recommended). Inoculate 1 µL of US IVD BTS solution onto each position.
2. Smear a thin film of each test organism onto an unoccupied US IVD 48 Spot Target position using a sterile wooden stick. Make sure that each sample is from an isolated colony.
3. Overlay each sample spot with 1 µL US IVD HCCA solution.

Note Make sure that the screw cap tube containing US IVD HCCA solution is tightly closed after use to minimize evaporation.

4. Allow the matrix-overlaid sample spots to dry at room temperature.
A homogeneous preparation should be observed for each test organism.
5. Perform MALDI Biotyper CA identification in accordance with the instructions in the *MALDI Biotyper CA System User Manual*.

extended Direct Transfer sample preparation method

The extended Direct Transfer method can be used to reanalyze test organisms that deliver a log(score) of <2.0 using the Direct Transfer method.

1. Select two positions on a US IVD 48 Spot Target (cross-joint positions are recommended). Inoculate 1 µL of US IVD BTS solution onto each position.
2. Smear a thin film of each test organism onto an unoccupied US IVD 48 Spot Target position using a sterile wooden stick. Make sure that each sample is from an isolated colony.
3. Overlay each sample spot with 1 µL 70% aqueous formic acid solution and allow the sample spot to dry at room temperature.
4. Overlay each sample spot with 1 µL US IVD HCCA solution.

Note Make sure that the screw cap tube containing US IVD HCCA solution is tightly closed after use to minimize evaporation.

5. Allow the matrix-overlaid sample spots to dry at room temperature.
A homogeneous preparation should be observed for each test organism.
6. Perform MALDI Biotyper CA identification in accordance with the instructions in the *MALDI Biotyper CA User Manual*.

Extraction sample preparation method

The Extraction method can be used to reanalyze test organisms that deliver a log(score) of <2.0 using the Direct Transfer method.

The Extraction method must be used to reanalyze test organisms that deliver a log(score) of <2.0 using the Direct Transfer and extended Direct Transfer methods.

1. Select two positions on a US IVD 48 Spot Target (cross-joint positions are recommended). Inoculate 1 µL of US IVD BTS solution onto each position.
2. For each test organism, pipette 1 µL of test organism extract (prepared in accordance with the instructions in the MALDI Biotyper CA System User Manual) onto an unoccupied US IVD 48 Spot Target position.
3. Allow the sample spots to dry at room temperature.
4. Overlay each sample spot with 1 µL US IVD HCCA solution.
Note Make sure that the screw cap tube containing US IVD HCCA solution is tightly closed after use to minimize evaporation.
5. Allow the matrix-overlaid sample spots to dry at room temperature.
A homogeneous preparation should be observed for each test organism.
6. Perform MALDI Biotyper CA identification in accordance with the instructions in the *MALDI Biotyper CA System User Manual*.

6 Manufacturer



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**For consumables orders, PO questions and Service Contract quotes, please call
+1 (877) 442 2231 during business hours.**

Ordering Information

Product	Part Number
US IVD HCCA portioned	# 604531

604531

Descriptions and specifications supersede all previous information and are subject to change without notice.

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